

## REMARKS

Claims 1-7, 9-11, and 15-17 are pending in the application.

Claims 1-3, 7, and 11 are rejected on various grounds under 35 U.S.C. § 102 and § 103.

### I. **Rejection Under 35 U.S.C. § 102(b) Based Upon U.S. Patent No. 5,840,746.**

The Examiner has rejected claims 1-3, 7 and 11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,840,746 of Ducharme, *et al.* ("Ducharme"). The Examiner reasons that Ducharme teaches a pharmaceutical composition comprising an oil-in-water emulsion and NSAIDs which are dispersed in an emulsion. The drugs in Ducharme, according to the Examiner, are COX-1 and COX-2 inhibitors, and the oily phase of the emulsion may be a vegetable oil such as arachis oil which, the Examiner contends is a hydroxylated oil. The applicants respectfully traverse the rejection.

Ducharme is not prior art to the instant application under 35 U.S.C. § 102(b). The § 102(b) date of Ducharme is November 24, 1998. This date is not more than one year prior to the effective filing date of this application, October 24, 1998. Thus, Ducharme cannot be cited against this application under 35 U.S.C. § 102(b) and it is requested that this rejection is withdrawn. However, assuming *arguendo* that Ducharme was prior art to the instant application, it is not anticipatory, for it does not teach each element of the invention as claimed. Ducharme describes a method of treating neurodegenerative diseases such as Alzheimer's disease, which includes administration of a therapeutically effective amount of a non-steroid COX-2 inhibitor to a patient. Ducharme discloses oral administration in the form of tablets or capsules is preferred. Col. 2, ll. 45-46. Additionally, Ducharme states that the pharmaceutical compositions of the Ducharme invention may also be in the form of oil-in-water emulsions, wherein the oily phase may be a vegetable oil, such as olive oil or arachis oil, or a mineral oil, such as liquid paraffin or mixtures of these. Col. 11, ll. 1-4.

Ducharme does not anticipate the invention as it is missing at least two elements of the invention as claimed. First, there is no disclosure in Ducharme of an oil-in-water in which 50 weight percent of the drug included in the composition is dissolved in the oil phase of the oil-in-water emulsion. There is simply no such disclosure in Ducharme.

Moreover, Ducharme does not disclose a drug containing an oil-in-water emulsion in which the oily phase is a hydroxylated oil. The Examiner suggests that arachis oil is a hydroxylated oil. This is incorrect. Arachis oil does not contain hydroxylated fatty acids. See, Specification at page 4, paragraphs 24-27 (defining hydroxylated oils); see *id.* at paragraph 27 (excluding arachis oil). The information known to a person of skill in the art confirms this definition. Arachis oil has a hydroxyl value of only 2.5 to 9.5 whereas castor oil, a hydroxylated oil within the definition of the Specification, has a significantly greater hydroxyl value, 161 to 169. See, the Merck Index, 12<sup>th</sup> ed., 1996 at 1213, 311-12 (a copy of which is enclosed herewith).

Accordingly, for at least these reasons the disclosure of Ducharme does not teach or suggest each element of the invention as claimed, and does not anticipate it. Reconsideration and withdrawal of the § 102(b) rejection based upon Ducharme is respectfully requested, as it is not prior art against the application and, assuming *arguendo* it were proper prior art under another subpart of § 102, it does not teach or suggest each element of the claims.

**II. Rejection Under 35 U.S.C. § 103(a) Based Upon Ducharme in View of U.S. Patent No. 6,096,728.**

The Examiner has rejected claims 1-7, 9-11, and 15-17 under 35 U.S.C. § 103(a) as being unpatentable over Ducharme taken in combination with U.S. Patent No. 6,096,728 of Collins, *et al.* ("Collins"). The Examiner applies Ducharme as in the anticipation rejection.<sup>1</sup>

The Examiner concedes that Ducharme does not teach a particular non-steroidal anti-inflammatory drug, but relies on Collins' teaching of a pharmaceutical composition comprising flurbiprofen and ibuprofen as well as its teaching for the treatment of pain in Parkinson's disease. The Examiner asserts that Collins also teaches compositions comprising COX-2 inhibitors and generally teaches use of "emulsions." Thus, relying on *In re Kerkhoven*, the Examiner asserts that it is *prima facie* obvious to combine the two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. Thus, the "expected result" would be a pharmaceutical composition

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<sup>1</sup> The applicants note that Ducharme is referred to as "(691)" and are puzzled by this reference as there is no '691 patent having Ducharme as the inventor cited in the application. Given the content of the § 103 rejection, the applicants assume the Examiner is applying Ducharme '746.

comprising an oil-in-water emulsion and a non-steroidal anti-inflammatory drug which is dispersed in the emulsion.

The applicants traverse the rejection.

The disclosure of Ducharme is discussed above, and is relied upon herein.

Collins teaches a pharmaceutical composition for the treatment of interleukin-1 mediated inflammatory diseases. The Collins composition contains a controlled release polymer and a proteinaceous IL-1 inhibitor. Polymers for use in the Collins composition include bulk erosion polymers, surface erosion polymers, cellulose, hyaluronan, alginate, collagen, gelatin, albumin, starches and dextran. The Collins compositions may include a non-steroidal anti-inflammatory drug and/or an analgesic. Further, as the Examiner herself has conceded in Paper No. 6 (a prior Office Action), Collins does not teach inclusion of a hydroxylated oil in the composition. Based upon the combination of Ducharme and Collins, the Examiner has simply failed to meet the requirements for a *prima facie* case of obviousness. The Ducharme-Collins combination omits at least two elements of the invention. Ducharme, as noted above, does not disclose a composition in an oil-in-water form, wherein at least 50 weight percent of the drug present in the composition is dissolved in the oil phase of the emulsion. Moreover, Ducharme does not disclose use of a hydroxylated oil. Collins does not remedy the deficiency, for it discloses neither an oil-in-water emulsion, nor use of a hydroxylated oil.

Moreover, despite the Examiner's protestations to the contrary, a person of ordinary skill would not have been motivated to make the combination suggested. There is nothing in either reference that would have encouraged the person of skill to make the combination, or that such combination would be reasonably successful.

The Examiner's reliance on *In re Kerkhoven* is misplaced. In *In re Kerkhoven*, two separate groups of claims were at issue (the Board considered claims 14 and 5 to be representative of each group). The Board found that claim 14, reciting a process for preparing a spray dried detergent containing detergent A and detergent B was obvious when the prior art combination expressly disclosed both (1) the process, and (2) each of the detergents. Claim 14, the Board reasoned, merely required the mixing of a known detergent A with a known detergent B, each made by the same process, each detergent composition having the same special purpose. *In re Kerkhoven* does not stand for the premise that if the general goal of two disparate

compositions is the same, they are *per se* combinable under U.S. law. Thus, the holding of Kerkhovan is wholly inapplicable in the present situation, and it cannot properly be the basis of a finding of motivation to support a *prima facie* case of obviousness.

In view of the foregoing, it is respectfully requested that the Examiner reconsider and withdraw the rejection of claims 1-3, 7, and 11, and allow all pending claims 1-7, 9-11, and 15-17 at the earliest opportunity.

Respectfully submitted,

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(Date)

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